



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

8280 00 MAY 25 P2:01

MAY 10 2000

Ms. Eve Mendoza
General Counsel
Natrol, Inc.
21411 Prairie Street
Chatsworth, California 91311

Dear Ms. Mendoza:

This is in response to your letter to the Food and Drug Administration (FDA), dated April 28, 2000, pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Prolab Nutrition, Inc., a wholly owned subsidiary of Natrol, Inc., is making the following claim, among others, for the product **ProAla**:

"Recent studies show that it can healp [sic] maintain healthy blood sugar levels."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease, namely hypertension. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Los Angeles District Office, Compliance Branch, HFR-PA240

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (file, r/f)
HFS-811 (r/f, file)
HFD-40 (Behrman)
HFD-310 (BWilliams)
HFD-314 (Aronson)
HFS-605
HFV-228 (Betz)
GCF-1 (Barnett, Nickerson, Dorsey)
f/t:rjm:HFS-811:5/2/00:70535.adv:disc47



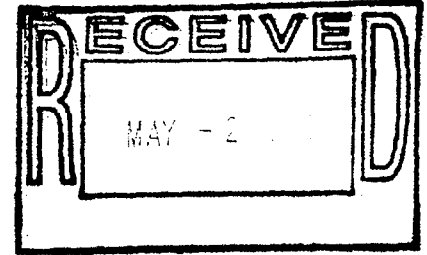
Quality Uncompromised™

April 28, 2000

VIA AIRBORNE EXPRESS & Regular Mail

U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals, HFS-450
200 C. Street S.W.
Washington, District of Columbia 20204

70535



Re: Prolab Nutrition Inc., a wholly owned subsidiary of Natrol, Inc.

Dear Sir or Madam:

I am the counsel for Prolab Nutrition, Inc., a seller of dietary supplement products, and a wholly owned subsidiary of Natrol, Inc., a manufacturer of dietary supplements.

On behalf of Prolab Nutrition, Inc. and pursuant to the requirement of Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. §343 (c) (6), your Agency is hereby notified that Prolab Nutrition, Inc. proposes to make statements of "nutritional support", as described in 21 U.S.C. §343(1)(6)(a), for its dietary supplements as follows:

- (1) Creatine: Maximizes size, strength and endurance; Increase muscle peak and torque production.
- (2) ProAla: Alpha Lipic Acid is a powerful antioxidant with health promoting properties unique to this compound. This powerful compound helps quench exercise and age related oxidative stress. Recent studies show that it can help maintain healthy blood sugar levels.
- (3) ProEFA: Provides a rich source of essential fatty acids in combination with other long change polyunsaturated fatty acids to help maintain optimal health and efficient metabolism. If you are looking to balance blood lipids while maintaining optimum circulation, ProEFA can help you reach your goals.
- (4) ProFLEX: This professional strength formula is designed to support and promote healthy joint function in the hard training cycle.
- (5) ProGrowth: Helps support stamina and strength and maintain and promote lean body mass.
- (6) ProHMB: Muscular support nutrient. It has been shown that in certain "high demand" situations dietary supplementation of HMB may be necessary to maintain optimum muscle cell and immune integrity.

21411 Prairie St.
Chatsworth, CA 91311

Tel: 818.739.6000

Fax: 818.739.6001

www.natrol.com

- (7) ProTECT: ProTECT helps support a healthy immune system and thereby promotes optimum health and recovery.

(8) ProVate2: In combination with a low fat/calorie diet and exercise program offers superior metabolic efficiency for the overall increase in energy levels and weight reduction.

(9) ProZMA: Enhances muscular strength.

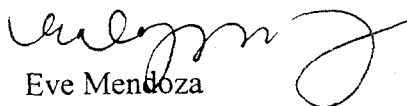
(10) X-tra Energy: Helps support energy levels and maintain alertness.

Please be advised that the label of each of the above dietary supplement products includes the statement that "The FDA has not evaluated these statements. This product is not intended to diagnose, treat, cure or prevent disease."

If you have any questions regarding the foregoing, do not hesitate to contact the undersigned at your convenience.

Sincerely,

NATROL, INC.


Eve Mendoza
General Counsel

cc: Elliott Balbert